PATENT
Attorney Docket No. **VACCINE-07083**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	David R. Milich *et al.*		
Serial No.:	10/630,070	Group No.:	1648
Filed:	07/30/2003	Examiner:	Salvoza, M.F.
Entitled:	**Rodent Hepatitis B Virus Core Proteins As Vaccine Platforms And Methods Of Use Thereof**		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **May 10, 2006**.

By: _____
Cliff Cannon-Cin

Dear Sir:

The citations listed below, copies of non-U.S. patents and published applications attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application:

- U.S. Patent No. 5,990,085 to Ireland *et al.*, "Inhibin-HBc fusion protein," (1999);
- U.S. Patent No. 6,887,464 to Coleman *et al.*, "Advanced antigen presentation platform," (2005);
- U.S. Publication No. US 2003/0099668 of Bachmann *et al.*, "Packaging of immunostimulatory substances into virus-like particles: method of preparation and use," (2003);
- U.S. Publication No. US 2004/0054139 of Page *et al.*, "Modification of hepatitis B core antigen," (2004);

- U.S. Publication No. US 2004/0146524 of Lyons *et al.,* "Stabilized immunogenic HBc chimer particles," (2004);
- U.S. Publication No. US 2004/0152876 of Birkett, "Immunogenic HBc chimer particles having enhanced stability," (2004);
- U.S. Publication No. US 2004/0156864 of Birkett, "Immunogenic HBc chimer particles having enhanced stability," (2004);
- U.S. Publication No. US 20040219164 of Coleman *et al.,* "Advanced antigen presentation platform," (2004);
- U.S. Publication No. US 2005/0208068 of Milich *et al.,* "Malaria immunogen and vaccine," (2005);
- Japanese Patent Application Publication No. JP7252300 of Okamoto "Antigen fused protein from duck hepatitis virus and human hepatitis virus and its production," (1995) in Japanese with English translation of abstract and specification;
- PCT Publication No. WO 95/27083 of Milich *et al.,* "Method for diagnosing chronic hepatitis B virus infection," (1995);
- PCT Publication No. WO 99/40934 of Birkett, "Strategically modified hepatitis B core proteins and their derivatives," (1999);
- PCT Publication No. WO 00/46365 of Coleman *et al.,* "Advanced antigen presentation platform," (2000);
- Belnap *et al.,* "Diversity of core antigen epitopes of hepatitis B virus," Proc Natl Acad Sci USA, 100:10884-10889 (2003);
- Fietelson *et al.,* "Core particles of hepatitis B virus and ground squirrel hepatitis virus," J Virol, 43:687-696 (1982);
- Fietelson *et al.,* "Monoclonal antibodies raised to purified woodchuck hepatitis virus core antigen particles demonstrate X antigen reactivity," Virology, 177:357-366 (1990);
- Galibert *et al.,* "Nucleotide sequence of a cloned woodchuck hepatitis virus genome: Comparison with the hepatitis B virus sequence," J Virol, 41:51-65 (1982);
- Gallina *et al.,* "A recombinant hepatitis B core antigen polypeptide with the protamine-like domain deleted self-assembles into capsid particles but fails to bind nucleic acids," J Virol, 63:4645-4652 (1989);

- Kidd-Ljunggren *et al.,* "Genetic variability in hepatitis B viruses," J Gen Virol, 83:1267-1280 (2002);
- Koschel *et al.,* "Extensive mutagenesis of the hepatitis B virus core gene and mapping of mutations that allow capsid formation," J Virol, 73:2153-2160 (1999);
- Marion *et al.,* "A virus in Beechey ground squirrels that is related to hepatitis B virus of humans," Proc Natl Acad Sci USA, 77:241-2945 (1980);
- Mason *et al.,* "Virus of Pekin ducks with structural and biological relatedness to human hepatitis B virus," J Virol, 36:829-836 (1980);
- Milich *et al.,* "Immune response to hepatitis B virus core antigen (HBcAg): Localization of T cell recognition site within HBcAg/HBeAg," J Immunol, 139:1223-1231 (1987);
- Milich *et al.*, "Antibody production to the nucleocapsid and envelope of the hepatitis B virus primed by a single synthetic T cell site," Nature, 329:547-549 (1987);
- Milich *et al.*, "Comparative immunogenicity of hepatitis B virus core and E antigens" J Immunol, 141:3617-3624 (1988);
- Millman *et al.*, "Immunological Cross-reactivities of woodchuck and hepatitis B viral antigens," Infect Immun, 35:752-757 (1982);
- Ponzetto *et al.,* "Core antigen and antibody in woodchucks after infection with woodchuck hepatitis virus," J Virol, 52:70-76 (1984);
- Ponzetto *et al.,* "Radioimmunoassay and characterization of woodchuck hepatitis virus core antigen and antibody," Virus Res, 2:301-315 (1985);
- Pumpens and Grens, "Hepatitis B core particles as a universal display model: A structure-function basis for development," FEBS Letters, 442:1-6 (1999);
- Schodel *et al.,* "Immunization with recombinant woodchuck hepatitis virus nucleocapsid antigen or hepatitis B virus nucleocapsid antigen protects woodchucks from woodchuck hepatitis virus infection," Vaccine, 11:624-628 (1993);
- Shanmuganathan *et al.,* "Mapping of the cellular immune responses to woodchuck hepatitis core antigen epitopes in chronically infected woodchucks," J Med Virol, 52:128-135 (1997);

- Stannard *et al.,* "Antigenic cross-reactions between woodchuck hepatitis virus and human hepatitis B virus shown by immune electron microscopy," J Gen Virol, 64:975-980 (1983);
- Tarar *et al.,* "Expression of a human cytomegalovirus gp58 antigenic domain fused to the hepatitis B virus nucleocapsid protein," FEMS Immunol Med Microbiol, 16:183-192 (1996);
- Ulrich *et al.,* "Core particles of hepatitis B virus as carrier for foreign epitopes," Advances in Virus Research, 50:141-182 (1998);
- Werner *et al.,* "Serological relationship of woodchuck hepatitis virus to human hepatitis B virus," J Virol, 32:314-322 (1979);
- Zheng *et al.,* "The structure of hepadnaviral core antigens," J Biol Chem, 267:9422-9429 (1992); and
- Zlotnick *et al.,* "Localization of the C terminus of the assembly domain of hepatitis B virus capsid protein: Implications for morphogenesis and organization of encapsidated RNA," Proc Natl Acad Sci USA, 94:9556-9561 (1997).

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: May 10, 2006

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FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: VACCINE-07083	Serial No.: 10/630,070
		Applicant: David R. Milich *et al.*	
(37 CFR § 1.98(b))	(Use several Sheets If Necessary)	Filing or 371(c) Date: 07/30/2003	Group Art Unit: 1648

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	5,990,085	11/23/1999	Ireland *et al.*			
	2	6,887,464	05/03/2005	Coleman *et al.*			
	3	2003/0099668	05/29/2003	Bachmann *et al.*			
	4	2004/0054139	03/18/2004	Page *et al.*			
	5	2004/0146524	07/29/2004	Lyons *et al.*			
	6	2004/0152876	08/05/2004	Birkett			
	7	2004/0156864	08/12/2004	Birkett			
	8	2004/0219164	11/04/2004	Coleman *et al.*			

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	9	JP7252300	10/03/1995	Japan			X	
	10	WO 95/27083	10/12/1995	WIPO				
	11	WO 99/40934	08/19/1999	WIPO				
	12	WO 00/46365	08/10/2000	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	13	Belnap *et al.*, "Diversity of core antigen epitopes of hepatitis B virus," Proc Natl Acad Sci USA, 100:10884-10889 (2003)
	14	Fietelson *et al.*, "Core particles of hepatitis B virus and ground squirrel hepatitis virus," J Virol, 43:687-696 (1982)
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